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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAKELARIS, SALLY A

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/10/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/898,566

Applicant(s)

TOWN ET AL.

Examiner

Sally A Sakelaris

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. This action is in response to Paper No. 8, filed December 5, 2002. Applicants arguments presented in the response of Paper No. 8 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn.

2. This application contains claims 1-16 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bond et al., *PNAS* 1998 **95**, 9608-9613.

The claims are broadly drawn to a marker for determining the risk of developing substance dependency comprising the OPRM1 + 118A allele. Bond et al. teach the "identification of different single nucleotide polymorphisms (SNPs) in the coding region of the mu opioid receptor gene," the primary site of action for the most commonly used opioids, the most prevalent SNP is a nucleotide substitution at position 118 (A118G)"(Bond et al, page 9608). Furthermore, the reference teaches "the A118G variant receptor binds  $\beta$ -endorphin, an

Art Unit: 1634

endogenous opioid that activates the mu opioid receptor, approximately three times more tightly than the most common allelic form of the receptor.” As a whole, the reference teaches that “SNPs in the mu opioid receptor gene”, as exemplified by A118G, “can alter binding and signal transduction in the resulting receptor and may have implications for normal physiology, therapeutics, and vulnerability to develop...addictive diseases”(Bond et al., page 9608). In particular, Bond teaches isolated nucleic acids comprising an A at nucleotide position +118 of the coding region of the OPRM1 gene and purports that the polymorphism “may have implication for normal physiology, therapeutics, and vulnerability to develop or protection from divers diseases including the addictive diseases”(Page 9608). Therefore, all of the limitations of the instant claim are anticipated by Bond et al..

In addition, with respect to Claims 17-20, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In the instant case, the SNP at position 118(A118G) taught by Bond et al. is no different from the instantly claimed marker for determining the risk of developing substance dependency comprising the OPRM1 + 118A allele(see MPEP 2111.02). Furthermore, it is noted that the claims are broadly drawn to markers comprising the OPRM1 +118A allele. The specification does not clearly define what constitutes a “marker” and the claims do not clearly define the structure and length of the marker. Therefore, the claims read on any marker comprising the “A”

Art Unit: 1634

at nucleotide position +118. Bond et al. further teach primers comprising an "A"(pg. 9609) and thereby the primers of Bond meet the limitations of claims 17-20.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 17-20 are indefinite and vague over the recitation of "whole allele marker" because the claims do not set forth the identity of the polynucleotide "whole allele marker." For example, it is unclear whether the "whole allele marker" as stated in the claims represents the allele as a whole (eg. the complete locus, the complete OPRM1 gene or a cDNA comprising the +118A polymorphism), a smaller fragment thereof (eg. a fragment consisting only of the A at position +118), or a larger fragment of the OPRM1 gene containing the +118 allele. The claims should be amended to clarify exactly what is intended to be claimed by using the term "whole allele marker."

***Response to Arguments***

5. In the response of Paper No. 8, Applicant's traversal of several arguments is acknowledged:

A. With respect to applicant's arguments concerning the 112 1<sup>st</sup> Paragraph enablement rejection, applicant's arguments are persuasive to overcome the rejections of record because

Art Unit: 1634

from an "epidemiologic perspective, substantial data proves a significant pattern of association among dependencies for a range of legal and illegal drugs" and "further supported by genetic studies of families and twins." It is further noted that in the examples, the issue of most importance is that increasing drug use, regardless of the type, is associated with the increased frequency of the OPRM +118A genotype and undue experimentation would not be required to practice the invention as claimed in the present application.

B. With respect to the art rejection, applicants traverse the rejection on the grounds that Bond et al. does not demonstrate a relationship between the OPRM1 +118A genotype and any form of substance abuse and as a result does not anticipate the presently claimed invention.

With respect to applicant's comments concerning the Bond et al. 102(b) art rejection, their arguments and amendments were not convincing as the rejection was maintained *supra*.

Furthermore, applicant should note that the limitation in their claim of "determining the risk of developing substance dependency" does not distinguish the claimed marker over the nucleic acid of Bond because the claimed marker comprising the OPRM1 +118A marker is structurally identical to the nucleic acid of Bond et al. Additionally, applicant should note the following from Chapter 2111.01 of the MPEP:

If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir.

Art Unit: 1634

2000) (holding that the preamble phrase "which provides improved playing and handling characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

*Sally Sakelaris*  
3/5/2003

*Carla J. Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER